UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
THIS DOCUMENT RELATES TO:	Case Nos. 1:17-md-2804 1:18-op-45817
Track 8: Cobb County, Georgia	Judge Dan Aaron Polster

PUBLIX SUPER MARKETS, INC.'S OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

Five years ago the *Track One* plaintiffs asked this Court to hold as a matter of law that more than a dozen defendants—including manufacturers such as Purdue, independent distributors such as Cardinal, and self-distributing pharmacies such as Walgreens—violated their duties under the Controlled Substances Act. This Court denied that request as to *all* defendants, holding "the record is replete with disputes of material fact as to whether each Defendant complied with its obligations under the CSA, which preclude summary judgment." *In re Nat'l Prescription Opiate Litig. ("Track One MSJ Order")*, 2019 WL 3917575, at *10 (N.D. Ohio Aug. 19, 2019).

Now, the *Track Eight* Plaintiff (Cobb County, Georgia) makes the same request as to Publix. In so doing, Cobb County barely acknowledges the Court's *Track One* denial and asserts, without explanation, that the case for summary judgment here is somehow stronger than in *Track One*. *See* Br. (ECF 5437-1) 33. But the case for summary judgment against Publix is demonstrably much weaker for many reasons, not least of which is the disparate treatment the U.S. Drug Enforcement Administration (DEA) imposed on the *Track One* defendants compared to Publix.

Many *Track One* defendants were hit with DEA enforcement actions and reached settlement agreements regarding the very provisions of the Controlled Substances Act (CSA) and DEA regulations relied on by MDL plaintiffs, including Cobb County. *See, e.g., Track One MSJ Order*, 2019 WL 3917575, at *15 (distribution); *In re Nat'l Prescription Opiate Litig. ("Track Three Rule 50 Order")*, 589 F. Supp. 3d 790, 818–19 (N.D. Ohio 2022) (dispensing). But DEA has *never* threatened, let alone brought, any such enforcement action against Publix—including for the entire period such DEA enforcement actions were the responsibility of Cobb County's own DEA expert, Joseph Rannazzisi. In fact, when DEA prosecuted CVS in the oft-cited *Holiday CVS* case, Mr. Rannazzisi pointed to Publix as an exemplar to suggest CVS's dispensing patterns were

suspect. Ex. 1 ¶ 51. Mr. Rannazzisi's prior testimony, as well as the contemporaneous feedback of qualified, objective DEA representatives throughout the entire relevant period, reflects DEA's consistently favorable view of Publix's distribution and dispensing activities. DEA representatives have even gone so far as to commend Publix for its track record as a registrant. Ex. 2 at 45–46.

Cobb County seeks determinations both as to the scope of Publix's duties under the CSA and DEA regulations and as to Publix's purported breach of same.[1] And as to breach, Cobb County offers a misrepresented, self-serving, one-sided view of the record that ignores—because it filed its motion before it even received them—both the opposing opinions of Publix's experts as well as the deposition testimony of its own experts undermining its position.

Cobb County has the burden of proof and cannot ask the Court to make credibility judgments or weigh the evidence. Rather, the Court must take all evidence and reasonable factual inferences in the light most favorable to Publix as the nonmoving party. Under that standard, Cobb County's motion falls far short. Its distribution-based arguments cite expectations that a distributor will implement a process designed to identify suspicious orders so they cannot be shipped and can be reported to DEA. But Cobb County and its cadre of experts have not identified a *single* suspicious order that Publix's warehouse received, filled, shipped, and failed to report to DEA.

Cobb County's dispensing-based argument fairs no better. It cites to an expectation that Publix's pharmacists will exercise their professional judgment in an appropriate manner and not knowingly fill an illegitimate prescription. This "corresponding responsibility" principle connects the expectation that a physician will not knowingly write an illegitimate prescription—meaning a

[1] While Cobb County argues that Publix violated duties under both the federal CSA and the Georgia Controlled Substances Act (GCSA), it "simply refer[s] to Publix's 'CSA duties' throughout [its] brief," Br. 1 n.1, and agrees that "[f]or purposes of the present motion, there are no material differences between the duties imposed on Publix by the CSA and those imposed by the GCSA," Br. 31. Accordingly, Publix's response likewise addresses the Court's decisions regarding the CSA and refers to the duties the Court has announced as "CSA duties."

prescription not written for a legitimate medical purpose by a prescriber acting in the usual course of their professional practice—to the corresponding expectation that a pharmacist will not knowingly fill such a prescription. And here again, neither Cobb County nor its cadre of experts identifies a single instance in which a physician knowingly wrote an illegitimate prescription that a Publix pharmacist knowingly filled.

Because it does not identify any actual suspicious orders Publix's warehouse in fact shipped or any actual illegitimate prescriptions Publix's Cobb County pharmacists in fact knowingly filled, Cobb County's case necessarily relies on innuendo and inference. Its motion is premised on a suggestion, indeed outright speculation, that Publix must have shipped such orders and its pharmacists must have knowingly filled such prescriptions because Publix did not implement the types of processes Cobb County years later now demands. And to support its demands for these processes, Cobb County relies heavily on conclusory, contradicted, after-the-fact assertions offered by a stable of paid opinion experts applying today's knowledge, standards, and state-of-the-art along a continuum of more than a decade—a period during which both Publix's processes and DEA and industry standards continuously evolved in parallel. In the process, Cobb County ignores that the record is replete with disputes of material fact and competing professional opinions as to exactly what specific processes and practices, considered in the aggregate as of any specific point in time, were substantially adequate under DEA's generally stated requirements.

Notable in this regard is Cobb County's and its experts' insistence that there is a *single*, bright-lined way to comply with DEA rules that applies to all times and across all industry participants. DEA's longstanding position, however, is 180 degrees opposite. DEA (a) repeatedly refused registrants' requests to advise whether any method of compliance was adequate, (b) never provided detailed guidance to the pharmaceutical industry interpreting DEA's generalized and

vague requirements, and (c) when asked for such guidance, would only recite the same mantra—that each registrant must exercise its own discretion in determining what processes and practices it believes are sufficient based on its own individualized circumstances.

Determining whether plaintiffs have shown a CSA violation—*e.g.*, that defendants "did not *substantially* comply" with their purported duty "to take *adequate* measures to guard against diversion of prescription opioids"—raises precisely the sort of inference-driven, judgment-laden questions that the judicial system relies on juries to resolve. *Track Three Rule 50 Order*, 589 F. Supp. 3d at 796. Cobb County has not come close to showing that the record here compels a jury to find that Publix violated the CSA. The most the County can muster is its own experts' *ipse dixit*—which a jury is entitled to reject. The Court should therefore deny summary judgment.

LEGAL STANDARD

Summary judgment is appropriate only when there is no genuine issue of material fact. *Jones v. Producers Serv. Corp.*, 95 F.4th 445, 449 (6th Cir. 2024). When considering the record at summary judgment, the Court cannot make credibility judgments or weigh the evidence but instead takes all facts and reasonable factual inferences in the light most favorable to the nonmovant (*i.e.*, Publix). *Ahlers v. Schebil*, 188 F.3d 365, 369 (6th Cir. 1999).

ARGUMENT

Cobb County seeks an order that (1) sets out Publix's duties as a distributor and dispenser of opioids, and (2) finds that Publix violated those duties. Br. 1–4. The Court should deny that request because Cobb County's showing is inadequate and based on mischaracterizations of both the Court's prior orders and the record evidence. The Court consistently says the "CSA and its regulations do not specify exactly what 'effective controls and procedures' a pharmacy must use to prevent diversion of controlled substances." *In re Nat'l Prescription Opiate Litig. ("Track Three MTD Order on Reconsideration")*, 2020 WL 5642173, at *3 (N.D. Ohio Sept. 22, 2020). Instead,

juries must exercise their judgment to determine whether a defendant's actions were "adequate" under the circumstances. *Track One MSJ Order*, 2019 WL 3917575, at *10 (addressing distributor duties); *see also Track Three Rule 50 Order*, 589 F. Supp. 3d at 796 (addressing dispenser duties).

Cobb County can't show a jury *must* find Publix failed to "substantially comply" with the CSA. *Track Three Rule 50 Order*, 589 F. Supp. 3d at 796. Its arguments rest on out-of-context statements and contradicted expert testimony that a jury can reject. For these same reasons, the Court's *Track One MSJ Order* denied summary judgment—and here Cobb County's basis for summary judgment against Publix is demonstrably so much weaker. *See, e.g.,* 2019 WL 3917575, at *14–15 (denying summary judgment against Cardinal due to "genuine issues of material fact regarding," *inter alia*, "whether Cardinal '*substantially*' complied with its duties under the CSA," even though Cardinal conceded "it inadvertently failed to report 14,000 orders to the DEA" (emphasis in original)). The Court should conclude the same here, where Publix has not conceded it failed to report even one suspicious order or knowingly filled even one illegitimate prescription. Indeed, Cobb County hasn't identified *any* suspicious order that Publix failed to report to DEA, or *any* illegitimate prescription Publix knowingly filled.

I. Pharmacy Duties under the CSA as Articulated by the Court

Publix does not challenge the Court's orders regarding pharmacies' duties here but preserves its right to later raise the many arguments Defendants have raised on these points in prior filings, including arguments that have only been strengthened by recent federal caselaw, all as contemplated in ECF 4978 at 4 n.2. So restricted, Publix addresses Cobb County's motion in accordance with "the Court's Orders and rulings entered in other case tracks of this MDL," as to pharmacies' duties as distributors and dispensers under the CSA. ECF 4978 at 3.

A. The Court's orders describing pharmacies' distribution duties under the CSA

The Court says the CSA's principal requirements of a distributor include a "reporting requirement" and a "no-shipping requirement." *Track One MSJ Order*, 2019 WL 3917575, at *5. Under the "reporting requirement," a distributor must (a) "design and operate a system" to identify "suspicious orders of controlled substances" (known as a "Suspicious Order Monitoring System," or "SOM" system), and (b) report any identified "suspicious orders" to DEA. *Id.*; *see* 21 C.F.R. § 1301.74(b); *accord* Br. 26–27. Under the "no-shipping requirement," a distributor discovering a suspicious order must either "decline to ship it" or hold it and "conduct some 'due diligence.'" *Track One MSJ Order*, 2019 WL 3917575, at *5. A distributor can ship an order if its due diligence indicates the "order is not likely to be diverted into illegal channels." *Id.*; *see also id.* at *4 (when distributor due diligence confirms an order is not suspicious, it is "exempt . . . from the DEA's mandatory reporting and no-shipping requirements").

Importantly, a "distributor may choose from any number of different methods and algorithms when creating its SOMS." *Id.* at *6; *see also id.* at *10 (denying summary judgment because there was a genuine dispute "on what constitutes an effective SOMS"). And though DEA has broadly indicated that "suspicious orders" may include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," 21 C.F.R. § 1301.74(b), DEA rules "do not provide any guidance on how to apply these criteria and instead are silent as to what registrants must do to ensure that their 'systems' are compliant," Ex. 2 at 9–10; *see also* Ex. 2 at 9 (noting DEA offered only limited guidance on "requirements of a SOM system" and "criteria that identify or constitute suspicious orders"). And "whether a specific order is 'suspicious" … involve[s] questions of fact that will [] necessarily depend on the totality of individual circumstances." *Track One MSJ Order*, 2019 WL 3917575 at *7 n.8.

The CSA does not expect perfect compliance (nor is such a feat possible); instead, the question is whether a pharmacy "'*substantially*' complied with its duties under the CSA." *Track One MSJ Order*, 2019 WL 3917575 at *15 (emphasis in original); *see also* Ex. 2 at 9. DEA reviews a distributor's CSA compliance using "a number of factors, including, but not limited to, the type of activity conducted by the registrant." Ex. 2 at 9. And what constituted substantial compliance in years past cannot be viewed only through the prism of today's standards, but must consider that DEA and industry knowledge, standards, and state-of-the-art all have evolved over the relevant decade-plus time period.

B. The Court's orders describing pharmacies' dispensing duties under the CSA

Pharmacists and pharmacies have a "corresponding responsibility" under the CSA not to knowingly fill prescriptions that were not "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); *see Track Three MTD Order on Reconsideration*, 2020 WL 5642173, at *2–3 & n.2. This rule imposes three requirements on pharmacies: "(1) establish corporate procedures and policies that recognize the 'corresponding responsibility' of its pharmacists and require its pharmacists to adhere to it; (2) supply its pharmacists with the tools necessary to enable them to perform their 'corresponding responsibility;' and (3) develop and utilize a system for monitoring the compliance of its pharmacists with their legal duties." *Track Three Rule 50 Order*, 589 F. Supp. 3d at 818. And as with distribution duties, the "CSA and its regulations do not specify exactly what effective controls and procedures a pharmacy must use to prevent diversion." *Track Three MTD Order on Reconsideration*, 2020 WL 5642173, at *3 (quotation marks omitted). For example, "there is no absolute requirement … that a pharmacy must conduct a computerized red-flag analysis of each prescription before filling it" and "no explicit requirement that they use the prescription data they collect to prevent diversion." *Id.* (emphasis omitted). Rather, the bottom-line requirement is that

"a pharmacy may not fill a prescription that it knows or has reason to know is invalid and may not remain deliberately ignorant or willfully blind of the prescription information it has." *Id.*

Finally, CSA rules "mandate[] the collection and retention of some specific datapoints":

- the number of units or volume of such finished form dispensed;
- the name and address of the person to whom it was dispensed;
- the date of dispensing;
- the number of units or volume dispensed; and
- the written or typewritten name or initials of the individual who dispensed or administered the [controlled] substance on behalf of the dispenser.

In re Nat'l Prescription Opiate Litig. ("Track Three MTD Order"), 477 F. Supp. 3d 613, 625–26 (N.D. Ohio 2020) (bullets and semicolons added; quoting 21 C.F.R. § 1304.22(c)); *see also* 21 C.F.R. § 1304.21 (listing other mandatory documents); 21 U.S.C. § 827(a)(3) (requiring dispensers to maintain records "of each such substance . . . received, sold, delivered, or otherwise disposed of by him"). In other words, pharmacies must keep records of the controlled substances they sell and which pharmacists dispensed them to which customers.

Cobb County, however, insists that the CSA *also* requires pharmacies to keep records of "due diligence done to resolve a red flag prescription … so that the reasons either for filling or refusing to fill are preserved." Br. 15. That is incorrect. The *Track Three Rule 50 Order* it cites, Br. 15 (citing 589 F. Supp. 3d at 819), does not discuss recordkeeping, much less a requirement to document all red flags and steps taken to resolve them. Nor has the Court elsewhere recognized such a duty, and its decisions suggest just the opposite. *Cf. Track Three MTD Order on Reconsideration*, 2020 WL 5642173, at *3 ("[T]here is no absolute requirement, for example, that a pharmacy must conduct a computerized red-flag analysis of each prescription before filling it").

Further, the CSA and DEA regulations contradict Cobb County's purported "document every red flag and resolution" rule. Contrary to Cobb County's claim, Br. 29, CSA recordkeeping requirements clearly list the specific categories of documents pharmacies must maintain, and *none*

includes the resolution of red flags. *See* 21 U.S.C. § 827(a)(3); 21 C.F.R. §§ 1304.21, 1304.22(c). The DEA decisions that Cobb County cites, Br. 29–30, likewise don't support its position, as they simply emphasize the importance of the existing (but limited) recordkeeping requirements; they do *not* say those requirements extend to identifications or resolutions of red flags. *See Grider Drug 1 & Grider Drug 2*, 77 Fed. Reg. 44070, 44100 (DEA July 26, 2012) (discussing dispensing logs); *Paul H. Volkman*, 73 Fed. Reg. 30630, 30644 (DEA May 28, 2008) (same).

Because the CSA and DEA regulations do not include red flag resolutions among their recordkeeping requirements, the "long-established canon of statutory construction, *expressio unius est exclusio alterius*, 'the mention of one thing implies the exclusion of another,'" dictates that pharmacies are *not* required to keep such records. *Traverse Bay Area Intermediate Sch. Dist. v. Mich. Dep't of Educ.*, 615 F.3d 622, 630 (6th Cir. 2010) (quotation marks and citation omitted). The *Track Three MTD Order* noted that beyond the listed documents—which Publix indisputably maintains, *see, e.g.*, Ex. 3 at 19—there may be "*other* information a pharmacy *may choose* to collect about its own dispensing practices." 477 F. Supp. 3d at 625 (emphasis added). Congress (and DEA) specifically listed the items pharmacies must document, and "it is logical to conclude that it did so at the exclusion of" other items it chose not to list. *Traverse Bay*, 615 F.3d at 630.

Without textual support for a duty to document red flags, Cobb County attempts to cast its expert's *opinions* as law, portraying the due diligence process articulated by its expert, Carmen Catizone, as if it were part of the CSA's recordkeeping requirements. Br. 29–31 & nn. 97, 99, 101. Mr. Catizone opines, for example, that pharmacists must "clearly and explicitly document their evaluation of the evidence and their reasoning supporting their judgment to dispense or refuse to fill the prescription." Br. 29. Experts, however, cannot conjure new regulatory requirements on their own authority. In any case, Mr. Catizone's opinions regarding documentation of red flags are

directly contradicted by Publix's experts. Ex. 4 at 12–13 (Lucas Hill opining that there is no law or regulation requiring documentation and that such "extensive documentation of the detailed decision-making related to dispensing of any prescribed medication is extremely uncommon in pharmacy practice"); Ex. 5 at 12–13 (Stefanie Ferreri offering similar opinion). Indeed, the Director of the Georgia Drugs and Narcotics Agency testified that his Agency does *not* have any policy, guidance, or rules about documenting red flags because "red flags . . . [are] not . . . in the rule or the law," but are instead simply "an educational tool." Ex. 6 at 100:10–101:2.

After all, there is no universal, agreed-upon set of "red flags" pharmacists should consider when assessing the legitimacy of a controlled substances. This is a significant point of dispute between the parties. *See* Ex. 4 at 15–17 (Mr. Hill describing "lack of a recognized standard for identifying 'red flags'"); Ex. 5 at 12–13 (Ms. Ferreri explaining there is "no one definitive list of 'red flags'"); Ex. 7 at 72:17–21 (Mr. Catizone admitting that there was no written list of his purported 14 red flags that a Georgia pharmacist could reference). And dissensus on what qualifies as "red flags" underscores why the law does not impose a universal documentation rule. Notably, the DEA Pharmacist's Manual, which "is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the [CSA and DEA Regulations]" does not contain a single reference to "red flags." Ex. 8 at 7.

In short, federal law doesn't require pharmacies to document the identification and resolution of every "red flag"—a term not mentioned in the statute, rules, or Pharmacist's Manual. Such a duty is impractical and inconsistent with industry practice. The Court should reject it.

II. As in *Track One*, There Are Genuine Disputes of Material Fact That Preclude Summary Judgment on Breach of CSA Duties

Cobb County reluctantly acknowledges that in *Track One* this Court rejected similar attempts to establish defendants' breach of CSA duties at summary judgment. Br. 33. Yet it

insists—without confronting the parties' evidence or the Court's reasoning in *Track One*—that it is entitled to summary judgment because (it asserts) the evidence is "so clear." *Id.* It is not. Cobb County's motion fails for the same reasons plaintiffs' summary judgment motion failed in *Track One*: There are multiple, genuine disputes of material fact that the trier of fact must resolve.

A. There is ample evidence from which a reasonable jury could find Publix complied with its distribution duties under the CSA

On distribution duties, Cobb County principally argues that Publix did not have an adequate SOM system prior to 2019, Br. 8–15, and summary judgment is improper because a jury is entitled to reject that notion. And the Court has said that whether a "SOMS was adequate"—and whether a defendant "substantially" complied with its duties—are judgment-laden questions for the jury. *Track One MSJ Order*, 2019 WL 3917575, at *10, 15; *see also id.* at *12 (explaining that the effectiveness of a SOM system is a "significant factual issue[] to be determined by a jury").

This is not a close question. The Court faced this issue before, and what Cobb County cites as to Publix is far weaker than what prior plaintiffs argued when the Court denied summary judgment. *See Track One MSJ Order*, 2019 WL 3917575, at *10–11. The Court's *Track One MSJ Order* denied summary judgment as to Cardinal, a distributor, even though Cardinal "concede[d] that, from 2012 to 2015, it inadvertently *failed to report 14,000 orders to the DEA*." *Id.* at *14 (emphasis added). There is no similar concession here. And Cobb County—despite having significant records to comb through, including each order Publix distributed to its Cobb County stores—does not identify any suspicious order which Publix should have, but did not, report.

Further, the factual assertions underlying Cobb County's argument are contradicted by the evidence presented by Publix—in whose favor all facts must be construed. As explained below, during the two periods at issue (2006–2014 and 2016–2019), Publix used an effective, multifaceted approach to detecting suspicious orders. Summary judgment should therefore be denied.

1. DEA did not fault Publix's SOM systems, which were operational and effective

First, Publix SOM systems have always used a combination of technology and Publix personnel to identify, review, and report suspicious orders. Publix employees testified as to the existence and effectiveness of its SOM system. *See infra* (Counter-Statement of Facts) 34. Brian Rucker (a former DEA diversion investigator) reviewed the SOM systems Publix put in place from 2005 through the present and found that they were compliant with the CSA and DEA regulations. Ex. 2 at 24, 63. Further, DEA itself reviewed the different iterations of Publix's SOM systems multiple times over more than a decade and never found a violation, issued a recommendation, or admonished Publix for noncompliance. *See infra* 32–33. In fact, in 2015 DEA specifically *commended* Publix's compliance efforts. Ex. 2 at 45–46. Importantly, these real-time reviews were performed in the context of then-applicable DEA knowledge, guidance, standards, and state-of-the-art considerations. And Publix "acted reasonably in relying on its interactions with the DEA and state regulators … to confirm its understanding that its SOM system and programs, along with all of its anti-diversion processes and procedures, were appropriate and acceptable methods designed to meet the goal of SOM to prevent diversion of opioids." Ex. 2 at 15.

If there had been any significant issue with Publix's threshold, algorithms, or overall SOM system from 2005–2016, DEA would not have granted Publix a new, enhanced registration in 2016 to begin distributing Schedule II controlled substances. Ex. 2 at 47. As Cobb County's own DEA expert recognizes, the "due diligence" process Publix went through to obtain its 2016 registration involved an assessment of its physical security, recordkeeping, and ability to maintain effective controls against diversion—including more than a decade's worth of observations of Publix's historical compliance with the CSA and its regulations. Ex. 2 at 47 (citing Ex. 9, Mr. Rannazzisi's deposition transcript). Construing the evidence in Publix's favor, a jury could reasonably conclude

that DEA would not have issued Publix a new, enhanced registration if there were any indication that the registration would be inconsistent with the public interest, including non-compliance of the type Cobb County suggests is "so clear." Br. 33; *see* Ex. 2 at 47.

DEA did not find fault with Publix's SOM system for good reason. Publix's SOM system relied on software systems (PIMS, E-Supply Link, OrderInsite) that utilized thresholds and algorithms based on historical purchasing data to flag and stop orders exceeding those calculated limits. *See infra* 34–36. The SOM applications became more fine-tuned as the technology improved and as Publix's operations evolved over time. DEA recognizes threshold-based algorithms as a valid SOM control, and leaves to the registrant the decision where to set its thresholds. Ex. 2 at 26. Cobb County has offered no evidence to suggest that Publix's conservative thresholds were insufficient or set too high. *See, e.g.*, Ex. 9 at 363:15–17 (Mr. Rannazzisi admitting he has "never seen dispensing data from Cobb County . . . [o]r ordering data."). Nor does Cobb County offer evidence that *any* pharmacy threshold increase approvals were made in error, *see infra* 30–31, 37–38, much less any increase for a Publix pharmacy located *in Cobb County*. Br. 11–13; *cf. Track One MSJ Order*, 2019 WL 3917575 at *15 (denying summary judgment where distributor used a threshold-based SOM system and "present[ed] evidence to support its assertion that it only increased a customer's threshold based upon a legitimate change in circumstances"). And Publix's thresholds were always used in conjunction with other SOM controls, such as the review conducted by Publix pharmacy supervisors and the use of CII Pull Reports. *See infra* 30–31, 37–38; Ex. 2 at 27.

Cobb County cannot explain why a jury must find that Publix's SOM system was unlawfully ineffective. Instead, it merely nitpicks at Publix's systems, insisting that Publix should have tweaked its approach—without ever attempting to establish that the law *required* Publix to

do so. For example, Cobb County faults Publix for not earlier creating a centralized compliance department staffed by diversion analysts, *see* Br. 13, but Mr. Rucker has explained that that the "CSA and [DEA] Regulations do not impose a responsibility on registrants to have the specific position of 'diversion analyst.'" Ex. 2 at 22. Cobb County casts aspersions on Publix's choice of OrderInsite in 2020 because it was a "startup" company, Br. 14–15, but it has no evidence to show OrderInsite's SOM application (custom-designed for Publix's distribution system) is not effective SOM, and even Mr. Rannazzisi did not (and could not) so opine. Ex. 9 at 312:15–313:8.

Cobb County also heavily relies on *one sentence* of a 2018 internal memo to suggest that the E-Supply Link software was non-compliant with the CSA. Br. 9, 11, 33. But that one sentence is provably false and has been mischaracterized because Publix's SOM system from 2016–2020 (when Publix used E-Supply Link software) in fact flagged numerous orders of interest and prevented them from shipping (regardless of whether they were in fact confirmed to be suspicious), and resulted in confirmed "suspicious" orders being reported to DEA. *See infra* 33–36; Ex. 2 at 34 (expert opining that the system was "operational and did flag orders"). Moreover, characterizing the E-Supply Link system as not working because it appropriately flagged orders of interest but also flagged an excessive number of meaningless false positives does not translate into noncompliance with DEA rules. Ex. 2 at 34; Ex. 10 ¶ 15. Cobb County's complaints on this score also fail to confront the fact Publix never relied on E-Supply Link alone: "Publix was relying on many things beyond [the] E-Supply Link system to prevent diversion, and . . . the data supports the conclusion that these efforts were effective." Ex. 2 at 34. Particularly in light of the other testimony and evidence, this single document cannot support summary judgment.

Ultimately, the fact that DEA reviewed Publix's SOM system five times over the relevant period and never found Publix out of compliance—and in fact commended Publix's distribution

operations—fatally undermines Cobb County's contention that a jury *must* find a violation here. DEA *did* conclude Publix's SOM system was adequate; a jury certainly *could* conclude the same. *Cf. Track One MSJ Order,* 2019 WL 3917575 at *14 (denying summary judgment and emphasizing that at the time "DEA investigators viewed [the defendant's] reports as compliant with the CSA" even though DEA later changed its view). Because the jury is entitled to accept Publix's evidence on this point, Cobb County cannot establish a CSA violation as a matter of law.

2. Cobb County has no evidence Publix failed to report any "suspicious" order to DEA

While Cobb County devotes much of its brief to quibbling with Publix's process for detecting suspicious orders, it recognizes that at the end of the day it is outcomes that matter: "The main determinant of an effective suspicious order monitoring system is whether it effectively identifies suspicious orders." Br. 9. And though it asserts there were suspicious orders that Publix failed to report, it has not identified a single suspicious order Publix failed to report or should not have shipped to a Publix store in Cobb County. It simply insists that "[p]rior to 2019, Publix did not report a single suspicious order to the DEA," and that *some* of the orders Publix processed during this period must have been suspicious. Br. 9.

Such groundless speculation is insufficient to allow a jury to find in Cobb County's favor, much less *require* a jury to do so. A jury can easily conclude that, if the lack of reported suspicious automatically translated to evidence of noncompliance, DEA would not have renewed Publix's registrations, would have taken enforcement action against Publix (as it did with Publix's competitors and wholesale distributors), and/or would not have granted Publix a new license with additional authorization to handle Schedule II controlled substances. Moreover, Publix employees have testified that there were no suspicious orders discovered prior to 2018. *See infra* 33. This evidence, especially when construed in Publix's favor, indicates that this is because Publix did not

ship any suspicious orders to its own pharmacies, none of whom were outliers. As Mr. Rucker has explained, Cobb County has not (and cannot) establish that "(1) Publix failed to identify any suspicious order; or (2) there was any actual diversion occurring at any Publix pharmacy, let alone one located in Cobb County, Georgia, that resulted from an ineffective SOM system." Ex. 2 at 16.

Further, Cobb County's speculation overlooks the fact that Publix did not distribute any Schedule II controlled substances, including the vast majority of drugs at issue in this case, into Cobb County (or elsewhere), until 2016. Ex. 10 ¶ 5. Cobb County also ignores that Publix is not a traditional wholesale distributor but only distributes drugs to its own pharmacies—a meaningful distinction. Ex. 2 at 11. DEA has previously recognized that the inherent differences between a wholesale distributor and a self-distributor (such as Publix) might require different SOM systems. Ex. 2 at 12.[2] For example, whereas a typical wholesale distributor has no direct insight into the dispensing practices of its pharmacy customers, Publix has total oversight of its warehouse-to-store supply chain and real-time, continuous insight into its own pharmacies' dispensing practices. Ex. 2 at 11–12; *see infra* 33–38 (describing how Publix's SOM process is able to use store-level data). Publix's SOM process thus includes activities that Publix, as the distributor registrant, performs which provide it a "holistic view across its integrated operation from the warehouse to its pharmacies to its retail customers." Ex. 2 at 36. And "Publix maintains control over each shipment even after an order leaves the warehouse," unlike a traditional third-party distributor. Ex. 2 at 36.

Because Publix is a self-distributor, it is unremarkable that it had no suspicious orders to report prior to 2018—especially because Publix largely did not begin self-distributing Schedule II

[2] *See* Ex. 11 at 239:2–16 (DEA official, asked whether "it could be reasonable for a retail chain pharmacy [] to not have to include all of the compliance measures in its SOM systems that might be necessary for a distributor who distributes controlled substances to customers that the distributor does not own," testifying that "Yes, I agree there could be differences between the systems for those two organizations").

opioids until late 2016. As Mr. Rucker explains, "given its more limited self-distribution operation until, effectively, 2017, the strict controls focused on limiting orders and preventing diversion and its consistently below average dispensing of oxycodone and hydrocodone, it does not surprise me that Publix did not report any suspicious orders for the specific opioids at issue in this case until [2018]." Ex. 2 at 38. Publix knows its stores are not pill mills or other suspicious sources (*e.g.*, internet pharmacies). *Cf. Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36487, 36498 (DEA July 3, 2007) (distributor violated CSA when it supplied large orders of opioids to internet pharmacies and pill mills without due diligence). This practical difference matters to DEA, and it matters here.

The type of data DEA routinely uses to identify suspect registrants also bolsters the view that Publix was not distributing opioids pursuant to suspicious orders. As just one example, Publix pharmacies in Cobb County consistently dispensed lower-strength opioids on average than other pharmacies in Cobb County, and ordered opioids at levels *significantly below* other pharmacies—about 31% lower volumes than other pharmacies in Cobb County (including other pharmacies Cobb County is not claiming violated the CSA) and 50% lower volumes than the national average. *See* Ex. 3 at Ex. 3A (PDF page 107); *infra* 39–40. These circumstances make it even more clear a jury may find that Publix didn't fail to report suspicious orders prior to 2018.

Even if Cobb County had identified orders it alleges are "suspicious" in hindsight (it has not), the Court has already held that whether an order is "suspicious" is a question for the jury. *Track One MSJ Order*, 2019 WL 3917575, at *7 n.8 (whether an order is "suspicious" and when it is "discovered" are "both questions of fact that necessarily depend on the totality of individual circumstances." (quotation omitted)). Further, Publix shipped thousands of orders over a 13-year period; even if Cobb County were to characterize a handful of these as "suspicious," that would not be enough to prove Publix did not "substantially" comply with its CSA duties. *Id.* at *15.

For all of these reasons, as in *Track One*, there are numerous disputed material facts and competing expert opinions that preclude a finding that Publix failed to substantially comply with the CSA. The Court should deny summary judgment on this issue.

B. There is ample evidence from which a reasonable jury could find Publix complied with its dispensing duties under the CSA

Cobb County's arguments on Publix's purported dispensing duties fail for the same reasons: Cobb County has not shown that a jury is compelled to find Publix's dispensing practices violated the CSA, it mischaracterizes its expert's opinions on recordkeeping as statements of law, and it attempts to circumvent the role of the fact finder.

Cobb County's arguments on this issue boil down to three criticisms, none of which establishes a violation of Publix's duties under the CSA nor warrants summary judgment. Br. 34–35. First, it argues that Publix did not have a policy requiring its pharmacists to document red flags or their resolutions—but there is no such duty under the CSA. Second, it complains that Publix did not provide its pharmacists with some-still-unidentified red flag or prescriber analytics technology—but this ignores the technology and data that Publix did make available to its pharmacists, and the fact that the CSA does not specify the technology, if any, pharmacies must adopt. Third, it contends that Publix did not properly train its pharmacists to identify red flags—but this ignores the fact that the CSA does not require this specific training and ignores the many policies, trainings, tools, and other resources Publix has made available to its pharmacists.[3]

[3] Cobb County does not argue that it is entitled to summary judgment on the ground that Publix failed to substantially comply with the requirement that pharmacies not knowingly fill illegitimate prescriptions. Br. 34–35. For good reason: The Court has held that whether a prescription was "illegitimate" and should not have been filled is necessarily a fact-intensive inquiry best suited for the trier of fact. *Cf. Track One MSJ Order*, 2019 WL 3917575 at *7 n.8 (whether an order is "suspicious" is a "question[] of fact"). Nor do Cobb County or its experts even claim to know whether diversion actually occurred. *See* Br. 34 (arguing that 40% of 750,000 opioid prescriptions dispensed in Cobb County showed signs of "*possible* diversion" (emphasis added)); Ex. 7 at 100:9–13 (Mr. Catizone answering "correct" when asked whether his "prior testimony would mean that you do not have an opinion on how many of the 16,700 prescriptions were

1. The CSA imposes no duty to document red flags or their resolution, and regardless Publix pharmacists routinely documented their due diligence

Cobb County's first argument—that Publix failed to document resolution of red flags—fails at the outset because the CSA *imposes no such requirement*. As explained above, this Court has never articulated such a duty—and for good reason, as it contradicts the text of the CSA and longstanding industry practice. *See supra* at 8–10.

Further, the inference Cobb County seeks—that without documentation, jurors should presume resolution did not occur—is improper, much less *obligatory*. To support its contention that "it is reasonable to infer that diversion in fact occurred" absent documentation of resolutions, Cobb County cites this Court's decision denying summary judgment to the *Track One* distributor and pharmacy defendants in *In re Nat'l Prescription Opiate Litig.,* 2019 WL 4178617, at *3 (N.D. Ohio Sept. 3, 2019). Br. 23. That decision, however, does not mention documentation or deal with dispensing-related duties. And that decision simply denied defendants' summary judgment motion—meaning the Court's discussion construed the facts in the light most favorable to the plaintiffs. The decision thus provides no support for Cobb County's summary judgment motion; after all, just a few weeks earlier the Court, considering the same record, likewise denied the *Track One Plaintiffs'* summary judgment motion. *Track One MSJ Order*, 2019 WL 3917575, at *10–16.

Moreover, here the evidence shows that Publix pharmacists did assess and resolve red flags before dispensing controlled substances, including opioids. *See infra* 29–30. Even Mr. Catizone's review found instances of pharmacists' documenting their due diligence and resolution of red flags—he merely deemed it insufficient based on his flawed understanding of the CSA's recordkeeping requirements. Br. 25. For these reasons, it is false for Cobb County to state that

actually for an illegitimate purpose"). Cobb County's dispensing arguments thus consist only of criticisms of Publix's process to facilitate and monitor its pharmacists' compliance with their corresponding responsibility obligation—exactly the type of inference-driven, judgment-laden matter left to juries.

"there is virtually no evidence that due diligence was performed on any of" the prescriptions that were "red flagged" in Mr. Catizone's retrospective review. Br. 34. Publix's witnesses have testified that Publix pharmacists consistently reviewed prescriptions for red flags, and this testimony is corroborated by Publix's company documents. *See infra* 29–30. Particularly when construed in Publix's favor, this evidence allows a reasonable jury to find that Publix's licensed pharmacists followed industry practice (and Publix policy) to evaluate prescriptions for red flags. Ex. 5 at 26.

Because the CSA does not impose any duty to document "red flags" or their resolution, and because there is ample evidence Publix pharmacists did document their due diligence in reviewing prescriptions for controlled substances, Cobb County's motion should be denied.

2. Publix has provided its pharmacists with sufficient tools to perform their corresponding duty under the CSA

Cobb County's second argument is that Publix failed to provide its pharmacists with red flag identifying or prescriber-blocking technology—technology that Cobb County does not identify and does not even establish exists. Br. 34–35. Even if Cobb County had identified such a hypothetical tool that Publix did not adopt (which it has not done), this argument fails because the CSA does not require pharmacies to use such specific tools or technologies. As this Court has noted, "the CSA and its regulations do not specify exactly what 'effective controls and procedures' a pharmacy must use to prevent diversion of controlled substances." *Track Three MTD Order on Reconsideration*, 2020 WL 5642173, at *3. For this reason, the Court has held that "there is *no absolute requirement*, for example, that a pharmacy *must conduct a computerized red-flag analysis* of each prescription before filling it" *Id.* (emphasis added). On the contrary, the essence of a pharmacy's dispensing duty under the CSA is "that a pharmacy may not fill a prescription that it knows or has reason to know is invalid and may not remain deliberately ignorant or willfully blind of the prescription information it has (including computerized reports it generates)." *Id*.

Cobb County does not argue that Publix prevented its pharmacists from accessing relevant information Publix maintained. After all, Publix has consistently recognized that the pharmacy's role "is to give the pharmacist the tools they need to use good judgment and make a good decision" and to not interfere with a pharmacists' professional judgment in their "decision to dispense or not dispense." Ex. 12 at 47:2–20. Publix has fulfilled that role and provided its pharmacists with adequate tools to assist in performing their corresponding responsibility. *See infra* 27–30.

Rather than address the tools Publix provides its pharmacists, Cobb County insists Publix was required to collect *additional* information and conduct *additional* analyses. Br. 35. That is not what the CSA demands: Just as there is no requirement that a pharmacy "conduct a computerized red-flag analysis" before filling a prescription, *Track Three MTD Order on Reconsideration*, 2020 WL 5642173 at *3, there is nothing in the CSA requiring Publix to develop a "prescriber monitoring system" or a system "for corporate blocks for suspicious prescribers," Br. 35.

Cobb County's demand for more data and analysis also ignores the vast dispensing data Publix already makes available to its pharmacists. Publix has provided its pharmacists with prescription management software that enables them to view detailed prescriber and patient information, and that automatically blocks prescriptions from prescribers with invalid DEA registrations. *See infra* 28–29. Cobb County does not identify what further technology might exist that Publix could have utilized, even if it were required. Nor, when asked, could Cobb County's expert provide any example of such a technology. *See* Ex. 7 at 189:24–190:18. Indeed, Mr. Catizone testified that he is unfamiliar with Publix's ERX dispensing software and that he had, as a practicing pharmacist, never used an electronic dispensing software. Ex. 7 at 188:22–189:4.

Cobb County has also failed to explain how acquiring the information to disseminate prescriber blocks would be feasible. There is no system to alert pharmacies of the arrest,

indictment, or disciplinary investigation of a prescriber. *Cf.* Br. 23–24 (noting dates of indictment or arrest for several prescribers); Ex. 3 at 58–64 (describing limited number of fills by Publix pharmacies for those prescribers). For example, disciplinary actions initiated by the Georgia Composite Medical Board are confidential during the investigation, and can last up to a year or more depending on the complexity of the case. Ex. 13 at 137:7–140:22. Except for extreme cases, prescribers retain their licenses to prescribe medication (including opioids) throughout the investigation process. Ex. 13 at 137:20–138:5. And when the Board issues a decision, it neither directly communicates disciplinary information to pharmacies nor provides real-time disciplinary information; instead, pharmacies would have to regularly check the Board's website for decisions, which are often uploaded after a month-long delay. Ex. 13 at 146:1–148:18.

Cobb County's demand for additional, still-unspecified technological resources rests entirely on its expert's say-so. Publix's experts disagree, which at the very least raises a factual issue for the jury. *See, e.g., Phillips v. Cohen*, 400 F.3d 388, 399 (6th Cir. 2005) (explaining "it is up to a jury to evaluate what weight and credibility each expert opinion deserves"); *Veth Mam v. City of Fullerton*, 2013 WL 3367529, at *2 (C.D. Cal. July 5, 2013) (noting "jury was of course free to credit either expert's testimony"). Publix has provided its pharmacists with adequate tools and data to fulfill their corresponding duties under the CSA. Cobb County's argument that Publix should have adopted various other strategies is one for the jury, not summary judgment.

3. Publix trained its well-qualified pharmacists on identifying and resolving "red flags"

Cobb County's final argument again relies on duties that do not exist and on a misrepresentation of the evidence. Cobb County argues that Publix did not train its pharmacists to identify and resolve "red flags," Br. 34, but no such specific duty exists under the CSA. *Track Three MTD Order*, 589 F. Supp. 3d at 818 (holding that a pharmacy must "establish[] corporate procedures and policies" that recognize its pharmacists' "corresponding responsibility").

This argument further fails on the facts because Publix trained its already-well-educated pharmacists on diversion policies, including identifying and resolving potential signs of diversion.

Pharmacists come to Publix with years of education and training, including training on their duties under the CSA and anti-diversion tactics. *See infra* 25–26. And beyond the knowledge gained from their advanced studies, Publix provides its pharmacists significant training (including mandatory training), tools to identify potential signs of diversion (including its 2012 R&P Guide listing "suspicious circumstances" regarding controlled substances), and access to anti-diversion regulatory references through the Publix intranet. *See infra* 25–30; Ex. 5 at 19–22.

Rather than deny that Publix had policies, trainings, and other procedures related to controlled substances, Cobb County questions their effectiveness. This Court has held, however, that such judgment-laden questions constitute "significant factual issues [that must] be determined by a jury." *Track One MSJ Order*, 2019 WL 3917575 at *12. The Court should therefore deny Cobb County's summary judgment motion on this ground as well.

In sum, Cobb County's arguments misstate the law, mischaracterize the Court's decisions, and misrepresent the record evidence. Interpreting the evidence in Publix's favor, a reasonable jury could readily find that Publix satisfied all its legal duties under the CSA. As a distributor, Publix designed and operated a multi-faceted SOM system that flagged and halted orders from its pharmacies—and that allowed Publix to review and identify suspicious orders, which it reported to the DEA. As a dispenser, Publix relied only on licensed pharmacists, required them to comply with their duties related to dispensing controlled substances, and gave them many resources (in the form of training and technology) to facilitate their compliance with those duties. Cobb County insists all this was inadequate. But that is a question for a jury to decide.

CONCLUSION

For the foregoing reasons, the Court should deny Cobb County's motion.

PUBLIX'S COUNTER STATEMENT OF FACTS[4]

I. Publix Retail Pharmacy Operations.

Employee-owned Publix operates grocery stores, many with community pharmacies, across eight southeastern states. Ex. 14 ¶ 2. Publix's pharmacies have DEA registrations and state licenses. Ex. 14 ¶ 4; Ex. 15 at 4–6. Every Publix pharmacy is run by a pharmacist in charge who reports to a pharmacy supervisor, who reports to a pharmacy operations manager, who reports to a Director of Pharmacy Operations, who reports to the Sr. Director of Pharmacy Operations, who reports to Publix's Vice President of Pharmacy. Unlike competitors, Publix fills all of these positions with an experienced, licensed pharmacist. Ex. 16 at 167:7–13; Ex. 5 at 22; Ex. 14 ¶ 7.

Since 2006, Publix has operated a number of pharmacies within the territorial limits of Cobb County, many of which are located within incorporated cities and thus outside Cobb County's jurisdiction and enforcement powers. Ex. 14 ¶ 5. Publix employs qualified pharmacists and has always required them to comply with all federal, state, and local laws applicable to dispensing drugs, including controlled substances. *See, e.g.,* Ex. 5 at 24; Ex. 14 ¶ 6; Ex. 16 at 33:2–22; Ex. 17 at 8-47–48; Ex. 19 at 165:24–166:7.

Publix stands behinds its pharmacists when they exercise their professional judgment and comply with the law, including when a pharmacist decides not to fill a controlled substance prescription. *See* Ex. 18. To that end, Publix has always maintained policies, tools, and monitoring systems to support pharmacists in performing their corresponding responsibility and ensure appropriate dispensing. Publix did, and continues to, develop its policies, tools, and monitoring systems as technology, knowledge, and standards evolve.

[4] For brevity's sake, Publix has not responded to every out-of-context "fact" presented in Cobb County's brief, and simply notes that evaluating the importance of the one-off statements Cobb County highlights represents a classic value-laden judgment reserved for a jury.

Publix asked Dr. Stefanie Ferreri to evaluate its retail pharmacy tools, practices, and processes. Upon completing her review, Dr. Ferreri concluded that Publix followed industry standards for pharmacy inventory, technology, and training, and that it maintained a healthy work environment for pharmacists to exercise their professional judgment and appropriately dispense (and prevent diversion of) controlled substances. Ex. 5 at 19, 41.

A. Publix has policies and training addressing pharmacists' legal duties

Publix hires quality licensed pharmacists, who are trained through education and experience to exercise professional judgment when assessing the legitimacy of prescriptions and dispensing medication, including controlled substances. Ex. 5 at 6–9, 19; Ex. 16 at 33:2–11, 40:19–24; Ex. 19 at 143:2–12, 165:1–17. A pharmacist's education and training includes the assessment of potentially fraudulent or illegitimate prescriptions. Pharmacists must pass NAPLEX and MPJE exams, which examine applicants on the clinical and legal knowledge needed for their day-to-day professional responsibilities. Ex. 4 at 8. Pharmacists, therefore, come to Publix with significant education and well-trained on the Controlled Substance Act, corresponding responsibility, and how to identify illegitimate controlled substance prescriptions. Ex. 5 at 6–9.

In addition to their education and training, Publix provides its pharmacists with training on company policies and systems. Upon hire, pharmacists undergo a two-week training. Ex. 5 at 19–20. This includes computer-based trainings specific to Publix's policies and procedures, as well as training on regulatory references available through the Publix intranet, including Georgia Board of Pharmacy website, the DEA Diversion Control Program website, and the Georgia Drugs and Narcotics agency website. Ex. 5 at 19–20.

At the time of hire, Publix provides its pharmacists with the Publix Pharmacy References & Procedures Guide ("R&P Guide"). The R&P Guide includes Publix policies pharmacists must follow. Ex. 5 at 21. All Publix pharmacists must review the R&P Guide and affirm they have read

and understood it. Ex. 5 at 24; Ex. 46 (Publix Controlled Substances Policy).[5] The R&P Guide is located inside every pharmacy and is available in electronic form through Publix's intranet. Ex. 12 at 127:5–18.

As far back as 2007, Publix's R&P Guide contained policies and guidance on altered or forged prescriptions—which are commonly considered "red flags" of diversion. Ex. 5 at 23. As the industry's understanding of prescription abuse developed, Publix's policies developed in parallel. Ex. 5 at 24. In 2011, Publix circulated information regarding trends in prescription opioid abuse and recent related DEA guidance. Ex. 5 at 24. In 2012, it updated its R&P Guide to include a section on "Identifying Invalid Prescriptions" to give its pharmacists a "list of potential suspicious activity that may indicate an invalid controlled substance prescription is being presented," supplementing pharmacists' existing knowledge and training on identifying potentially invalid prescriptions. Ex. 5 at 24; Ex. 20 at 8-34. The R&P Guide includes guidance about handling and reporting fraudulent prescriptions, and cites the applicable federal regulations. Ex. 5 at 24; Ex. 20 at 8-34. According to Fred Ottolino (then Publix's Vice President of Pharmacy), these 2012 additions served as "a guide for the pharmacist . . . to make sure they think things through as they fill a prescription," though "[i]t's the pharmacist's judgment that [] is needed in filling these prescriptions." Ex. 12 at 140:14–21.

Publix provides its pharmacists with various continuing education opportunities to satisfy state licensing requirements and to stay up-to-date on developing pharmacy topics (including issues related to opioid diversion). This includes free access to Drug Store News and Pharmacist's

[5] Cobb County cites (Br. 17) the isolated statement of a single Publix pharmacist that her deposition preparation was "the first time I'd seen [the suspicious circumstances to consider when evaluating prescriptions for diversion] presented from within the R&P Guide." Ex. 21 at 44:5-45:8. This qualified statement has little weight even taken on its own terms, and certainly does not contradict the undisputed evidence that Publix provided the R&P guide to all of its pharmacists and required them to review it.

Letter, two reliable and reputable training materials. Ex. 5 at 20; Ex. 15 at 38–39. In 2016, Publix provided an opioid refresher shortly after the CDC guidelines for opioids were published. Ex. 5 at 21. And in 2019, Publix issued mandatory computer-based trainings for its pharmacists specific to opioids, including one that "provides a review of controlled substances rules, including prescriber and prescription requirements," and "helpful advice on how to determine if the prescription is legitimate or not." Ex. 22; *see also* Ex. 5 at 21.[6]

B. Publix makes available tools, resources, and data to assist pharmacists in exercising their corresponding responsibility under the CSA

Publix makes a variety of resources available to aid its pharmacists in fulfilling their corresponding responsibility. For example, its intranet gives pharmacists access to computer-based trainings, a morphine milligram equivalent (MME) calculator, the naloxone standing order guide, weekly internal Publix pharmacy memos, and other correspondence from Publix pharmacy leadership to keep pharmacists informed of industry developments, including those related to controlled substances and opioids. Ex. 5 at 20.[7] These weekly memos and other updates are regularly printed and posted in individual stores for all pharmacy workers to review. Ex. 5 at 20.

Publix also provides its pharmacists multiple technology tools that assist them in exercising their professional judgment in evaluating prescriptions. As Dr. Ferreri summarized, "[d]uring the time period of 2006-2021, many changes occurred within pharmacy technology." Ex. 5 at 27. And

[6] Publix disagrees entirely with Cobb County's misleading characterization of the opioid "task force," Br. 18–19, which was an informal opportunity for pharmacists to share their individual opinions on a topic of importance to their colleagues. Ex. 23 at 206:17–208:8.

[7] *See also* Ex. 24 (2008 Ottolino email regarding change in controlled-substance receiving process in light of theft); Ex. 25 (2010 Weekly Memo updating pharmacists regarding DEA guidance on electronic prescribing of controlled substances); Ex. 26 (2011 Weekly Memo informing pharmacists of Georgia PDMP legislation); Ex. 27 (2011 email from Pharmacy Operations Manager Mike King to Atlanta pharmacies forwarding information from the Georgia BOP regarding security paper requirements for controlled substances); Ex. 28 (2012 Weekly Memo regarding DEA Pharmacist's Manual on Corresponding Responsibility); Ex. 18 (2011 Ottolino memo to all pharmacy operations managers and pharmacy supervisors regarding prescription drug abuse and pharmacists "corresponding responsibility").

"Publix and its pharmacists changed with the times with regard to technology. Publix's pharmacy dispensing software was consistent with the standard of care at the times that the various programs were in use, and the software was updated in a timely and appropriate manner." Ex. 5 at 27.

One example of Publix's evolving technology is its implementation of the EnterpriseRx system in 2010. Ex. 5 at 27; Ex. 29 at 206:10–18. This system, developed by a leading healthcare technology firm, enabled pharmacists to more easily view detailed information (including information about the prescriber and patient, as well as store-level dispensing data) directly from their computer in the pharmacy. Ex. 5 at 27. This was a first in pharmacy technology; prior to ERX, "dashboards (and therefore data) were not housed with the pharmacy dispensing software." Ex. 5 at 27. By implementing ERX, Publix thus enabled its pharmacists "to have access to more information to make informed decisions about the populations they were serving and the prescriptions they were filling at their store. For example, Publix's current system highlights the prescription, prescriber or patient note tab in red if there are any notes present in the respective tab." Ex. 5 at 27. ERX also allows pharmacists to "see if a prescription for a Publix patient was filled at another Publix location." Ex. 5 at 28.

Publix has integrated another tool into the ERX program to assist its pharmacists in evaluating prescriptions. RelayHealth verifies "that DEA numbers entered for controlled substance prescriptions belongs to a prescriber that is authorized to write for controlled substances." Ex. 5 at 28. The system thus notifies "the pharmacist if the DEA number is not valid or active," and if it is invalid "Publix pharmacists cannot complete the dispensing workflow or dispense the medication." Ex. 5 at 28; *see also* Ex. 30 at 282:2–11. In other words, if the pharmacist enters an invalid DEA license into the system, there is a "hard stop," and the prescription cannot continue.

Ex. 12 at 70:7–71:18; *see also* Ex. 19 at 103:15–105:7 (describing how the system "block[s]" physician with an invalid DEA license "from being able to have a prescription filled").

Further, Publix complies with Georgia's PDMP requirements including and has provided its pharmacists access to the PDMP database since the database went live in 2013. Publix's 2012 R&P Guide update also provides guidance on how to identify invalid controlled substance prescription with reference to the PDMP—and did so even before Georgia's PDMP system was operational. Ex. 5 at 26; *see also, e.g.*, Ex. 31 at 8-63– 64 (advising pharmacists to check PDMP to identify and guard against invalid practitioner-patient relationships). Notably, neither the CSA nor Georgia law require pharmacists to consult the PDMP when filling a controlled substance prescription; instead, Publix provides these resources to its pharmacists and, consistent with Georgia law and expectations, relies on them to use their professional judgment to decide when use of the PDMP is necessary or helpful. Ex. 5 at 27. And Publix has invested in software that fully integrates the PDMP database into its own ERX system, making its use more streamlined for its pharmacists. Ex. 5 at 26–27.

As licensed professionals, Publix pharmacists are trusted to use these resources, in addition to their years of training and education, to exercise their professional judgment when assessing the legitimacy of a prescription. *See, e.g.,* Ex. 12 at 47:2–20; Ex. 5 at 22. And the evidence establishes that Publix pharmacists do in fact use these tools to assess the legitimacy of prescriptions and to refuse to dispense potentially fraudulent or illegitimate prescriptions. Ex. 32 (2018 email to Atlanta-area pharmacies about a prescriber who was incarcerated and adding note in ERX system); Ex. 16 at Ex. 6 (PDF pages 13–80) (emails ranging from 2015–2021 between Publix stores notifying each other of forged prescriptions and attempted fills); Ex. 33 at Ex. 27 (PDF pages 15–16) (2020 email from a pharmacy supervisor describing her decision not to fill prescription). Publix

pharmacists also routinely utilize the ERX system to document that they checked PDMP and either cleared red flags prior to dispensing controlled substances or refused to fill the prescription. *See* Ex. 5 at 36–37. As Dr. Ferreri observed, these notes make "apparent that [Publix] pharmacists are exercising their clinical knowledge regarding patient safety concerns for opioids." Ex. 5 at 37.

C. Publix monitors its pharmacists' compliance with Publix policies and applicable laws regarding the dispensing of controlled substances

In addition to providing policies, training, and resources to its pharmacists, Publix monitors their compliance. It has done so through several methods throughout the relevant period, including in-person store visits, audits of controlled substance data, quarterly compliance meetings by upper-level pharmacy management, and, since 2019, a dedicated, centralized compliance department.

Publix's pharmacy supervisors and pharmacy operations managers regularly conduct store visits and review store-specific CII Pull Reports to monitor dispensing activity. Ex. 5 at 21, 38–39.[8] CII Pull Reports show the percentage of controlled prescriptions, patients paying cash, total prescription county, and other prescription data for specific controlled substances such as oxycodone products for each Publix pharmacy, which pharmacy supervisors can and do use to monitor trends and CSA compliance. Ex. 2 at 29, 31, 37; Ex. 33 at 114:3–116:3.

During their visits to individual pharmacies, supervisors review hard copy and electronic prescription information for controlled substances. Ex. 5 at 38; Ex. 16 at 64:2–5. Supervisors also review dispensing decisions with pharmacists, verifying the information pharmacists used when exercising their professional judgment and making dispensing decisions. Ex. 5 at 38–39; Ex. 19 at 94:22–95:18; Ex. 16 at 87:16–88:2. Pharmacy supervisors discuss updated policies with their teams and give pharmacists feedback on the types of patient or prescriber scenarios that might indicate a prescription might be illegitimate. Ex. 5 at 21, 38. Working with pharmacy warehouse

[8] *See* Ex. 33 at 75:21–76:16; Ex. 19 at 68:22–70:5; Ex. 16 at 16:14-17:6; Ex. 12 at 87:11–19, 204:9–205:1.

operations, Publix identifies whether a pharmacy location has had an increased percentage of controlled substances of its total drug sales; if so, it will task a pharmacy supervisor with examining that location and determining the cause of the increase. Ex. 12 at 83:11–19; Ex. 5 at 39.

Finally, as part of its commitment to compliance, Publix has always had an extra layer of review in addition to the in-field efforts of its pharmacy supervisors and operations managers. As far back as 2005, Publix conducted quarterly compliance meetings to discuss Publix's global pharmacy operations (distribution and dispensing). *See* Ex. 2 at 27, 34; Ex. 12 at 100:12–24, 159:11–21, 182:14–192:22; Ex. 12 at Ex. 13 (PDF pages 31–76) (minutes of October 2006 compliance team meeting). Mr. Ottolino, who sat on the compliance team, described how the compliance team used these quarterly meetings to review a variety of metrics related to diversion and any necessary action items to address areas of concern. *See* Ex. 12 at 182:14–192:22.

II. Publix Pharmacy Warehouse Operations

Since 2005, Publix has operated a pharmacy warehouse where it stored prescription drugs, including certain controlled substances, before transferring them to restock Publix pharmacies. The warehouse maintains a DEA distributor registration and has never been a wholesale distributor to any third party. Ex. 15 at 4; Ex. 2 at 23–24. Importantly, in September 2014 DEA relisted hydrocodone combination products to Schedule II, and Publix ceased warehousing them until it opened its new pharmacy warehouse in late 2016, when it was authorized by DEA to warehouse Schedule II controlled substances. Ex. 15 at 4, 7; Ex. 34 at 184:19–185:4; Ex. 2 at 23–24.[9]

[9] Cobb County's chart (Br. 6) purportedly depicting Publix's distribution of total dosage units of opioids—across the entire company, not just in Cobb County or even Georgia—omits this critical fact. The substantial increase in 2016 and 2017 (which declines and plateaus thereafter) obviously reflects the opening of Publix's warehouse—not, as Cobb County contends, that Publix "filled the void left by other distributors." Br. 6. Publix lawfully opened its warehouse pursuant to DEA authorization, and that legitimate business decision does not provide evidence to support any of Cobb County's claims.

A. Publix's suspicious order monitoring systems are effective

Throughout its time as a registered distributor, Publix has had an effective SOM system—which has always taken a multi-tiered and holistic approach to evaluating orders placed by Publix retail pharmacies. As DEA and industry, knowledge, standards and state-of-the-art continuously evolved, Publix's system developed in parallel. Publix asked Mr. Rucker to evaluate its SOM systems, practices, and processes as they have existed over the relevant time period and considering applicable industry standards. And Mr. Rucker succinctly concluded that Publix's SOM program has "clearly [been] effective in preventing diversion." Ex. 2 at 20.

Mr. Rucker's favorable conclusions regarding Publix, its SOM systems, and its controls against diversion are reinforced by the contemporaneous feedback of qualified, objective DEA diversion investigators who conducted inspections throughout the relevant period. Publix's warehouses and SOM systems are regularly subject to inspections by DEA representatives—who have access to the physical warehouse, personnel, records, ARCOS data, prior inspection reports, and suspicious-order reports. Ex. 2 at 24, 38–50. The DEA conducted five such inspections from 2006–2019 and *none* of these inspections resulted in any adverse action against Publix:

2008: After inspection that specifically reviewed Publix's SOM system, Ex. 36 at 11005, DEA closed its case without any recommendations or admonishments, Ex. 2 at 42–43.

2011: After auditing Publix's SOM system and orders of controlled substances (including hydrocodone products), DEA concluded there were no violations. Ex. 37; Ex. 2 at 43–44.

2015: After reviewing controlled-substances orders from 2013–2015, Publix's SOM system, and Publix's Controlled Substances Anti-Diversion Processes, Ex. 45, DEA closed its case without issuing violations or recommendations, Ex. 38; Ex. 2 at 44–45.

2017: DEA audited Publix's controlled-substances orders from prior fiscal year (which covered the first six months that Publix was self-distributing Schedule II drugs) and noted that its audit "revealed no suspicious transactions." Ex. 39 at 10823; Ex. 2 at 48.

2019: DEA again audited Publix's controlled-substances orders and conducted a thorough review of Publix's SOM system, concluding there were no issues with Publix's orders and closing its inspection in 2021 without taking any adverse action. Ex. 40; Ex. 2 at 49.

Indeed, the DEA *commended* Publix's distribution practices. In 2015, it contacted Publix to have a meeting to discuss "a good thing." Ex. 2 at 45–46; Ex. 41. At the meeting, DEA informed Publix Procurement Manager Chris Hewell that Publix was handling its self-distribution activities well and encouraged it to continue operating in the same fashion. Ex. 2 at 46.

Publix has also always reported orders it determined to be suspicious. Ex. 10 ¶ 14. Until 2018, Publix's companywide distribution operations had no suspicious orders to report to DEA. Ex. 34 at 182:20–184:4; 279:23–280:1; Ex. 35 at 32:2–7. And Publix has never had any suspicious order from a pharmacy located in Cobb County (though from 2018 to 2021 Publix detected and reported to DEA more than 150 suspicious orders from pharmacies outside Cobb County, with only a handful from Georgia). Ex. 35 at 33:1–6, 26:13–27:18, 123:12–17. Nor has Cobb County identified a single suspicious order that Publix's warehouse fulfilled and shipped, or which Publix should have reported to DEA (and did not)—anywhere, let alone from a Cobb County pharmacy.

B. The components of Publix's SOM systems

Publix's SOM system incorporates (1) electronic order-monitoring technology that flags orders of interest (which were not shipped regardless of whether they were found to be suspicious in fact), (2) Publix employees who personally review flagged orders (orders of interest) and analyze dispensing trends, (3) centralized controlled substance ordering system (CSOS) Administrator order review, and (4) other review. *See* Ex. 34 at 182:9–18; Ex. 2 at 24, 27–29.

1. Technology to identify and block orders of interest

From 2005-present, Publix has used several technology solutions to identify orders of interest or "flagged orders" placed to its pharmacy warehouse. Every SOM technology solution used at Publix, and discussed below, always blocked and prevented the Publix pharmacy warehouse from shipping any order of interest or "flagged order" regardless of whether (or not) it was later deemed to be suspicious. During the entire period that Publix has distributed controlled substances, it has had a SOM system that implemented "reasonable controls" to "flag[] orders of interest and then cut[] them so they could not make it to the store in order for those [orders] to be investigated." Ex. 19 at 218:7–16. The point was made crystal clear by Mr. Hewell, who testified that an order of interest *never* left Publix's warehouse. Ex. 34 at 170:3-6.

Publix's technology solutions to identify orders of interest are set forth below: [10]

Period	Location	Controlled Substances	Relevant Opioids	Technology
2005–09/2014	1950 Sand Lake Rd Orlando, FL	Schedules III–V No Schedule II	Only Schedule III Hydrocodone Combination Products	PIMS
09/2014–10/2016	1950 Sand Lake Rd Orlando, FL	Schedules III–V No Schedule II	None	PIMS 2.0
10/2016–2020	10400 Rocket Ct Orlando, FL	Schedules II–V	All	SOMLink
2020–Present	10400 Rocket Ct Orlando, FL	Schedules II–V	All	OrderInsite

When Publix began distributing Schedule III – V drugs in 2005, it used an internally designed system called Publix Inventory Management System ("PIMS") to identify and block suspicious orders. Ex. 10 ¶ 6; Ex. 35 at 45:2–25. This system imposed conservative thresholds on

[10] In September 2014, DEA relisted hydrocodone combination products to Schedule II, and Publix ceased warehousing them until it opened its new pharmacy warehouse in late 2016 and was authorized by DEA to warehouse Schedule II controlled substances. Ex. 15 at 4, 7; Ex. 34 at 184:19–185:4; Ex. 2 at 23–24.

orders; if an order triggered the threshold, PIMS would automatically cut the order (*i.e.*, Publix would not ship the order to the pharmacy). Ex. 2 at 26 (citing Ex. 34 at 147:16–148:12; Ex. 35 at 57:12-16, 58:3-19). The thresholds limited the quantity and frequency with which Publix pharmacies could order controlled substances, and were tied to the historic utilization pattern of all Publix pharmacies. Ex. 2 at 26. From 2005–2012, these conservative order thresholds applied in the same manner to all Publix pharmacies. Ex. 2 at 26 (citing Ex. 35 at 58:3–16).

In 2012, Publix implemented new functionalities to PIMS ("PIMS 2.0"). Ex. 34 at 180:10–18; Ex. 2 at 27. These enhancements allowed Publix to set individualized thresholds per pharmacy and for individual drug molecules based on historic utilization patterns. Ex. 35 at 58:18–60:10; Ex. 2 at 27–28. Like the prior iteration, the PIMS system in place in 2012 through 2016 would immediately cut any flagged order. Ex. 2 at 29; Ex. 34 at 165:12–23; Ex. 10 ¶ 7. Over the course of the entire 2005–2016 period, Publix discovered no suspicious orders among its flagged orders, and therefore did not report any suspicious orders to DEA. Ex. 10 ¶ 9; Ex. 35 at 32:2–7.

In 2015, while preparing the new warehouse it would use to distribute Schedule II controlled substances, Publix used the pause as an opportunity to build on the system commended by the DEA in 2015—that is, "to enhance [its] suspicious order monitoring process," as part of Publix's "culture of continuous improvement." Ex. 34 at 199:12–20, 205:10–23. Publix contracted with a third-party vendor, E-Supply Link, to replace PIMS with a new SOM software called "SOMLink." Ex. 34 at 180:24–181:5; Ex. 2 at 32–33; Ex. 10 ¶ 10.

As with PIMS, SOMLink analyzed each line item within an order for controlled substances received by Publix's warehouse, and would automatically cut any flagged line item from an order—which meant no flagged order was ever shipped from Publix's warehouse. Ex. 2 at 33; Ex. 10 ¶ 11. And E-Supply Link provided greater functionality than PIMS, including over 15 different

types of tests or algorithms that could be applied to detect potentially suspicious orders. Ex. 42; Ex. 10 ¶ 11. With the SOMLink technology in place, Publix applied for and received a new DEA registration authorizing it to warehouse and self-distribute Schedule II drugs *See supra* at 31.

Once in use, Publix observed that SOMLink did not work, in that it flagged many excessive false positives (in addition to flagging items of interest). Ex. 2 at 34; Ex. 10 ¶ 15.[11] Because E-Supply Link was unwilling to work with Publix to modify its program to reduce excessive false positives, Publix ultimately decided to replace it with a different order monitoring software. Ex. 10 ¶ 15.

From 2018 through 2020, Publix transitioned from E-Supply Link to a custom SOM solution developed by OrderInsite. Ex. 34 at 181:6–22; Ex. 10 ¶ 15. Because the OrderInsite system was tailor-made for Publix, it took time to develop and implement. Ex. 2 at 35; Ex. 10 ¶ 15. With its enhanced functionalities, OrderInsite provides Publix additional scrutiny of controlled-substances orders and maintains daily, weekly, and monthly thresholds on a rolling 30-day basis. Ex. 2 at 35 (citing Ex. 34 at 181:19–182:6). The system also accounts for orders fulfilled by third-party distributors. Ex. 2 at 35 (citing Ex. 43). OrderInsite became operational at Publix in 2020, and Publix continues to the software as part of its multi-tiered SOM system. Since launching OrderInsite, Publix has continued to report all suspicious orders to DEA. Ex. 10 ¶ 16.

2. Publix pharmacy personnel were notified and tasked with reviewing flagged orders

From PIMS, to E-Supply Link, and now Order Insite, all of Publix's SOM technology programs have automatically alerted pharmacy personnel via email to flagged orders in order to facilitate follow up and reporting, if necessary, of actually suspicious orders.

[11] As explained by Mr. Rucker, the E-Supply Link report provides "critical context and reveals that between 2016 and 2020, the E-Supply Link system was flagging orders for different products (including opioids), and those orders were reviewed and subject to due diligence by Publix personnel." Ex. 2 at 34.

If an order was flagged by the PIMS system, both the relevant pharmacy manager and pharmacy supervisor for the ordering store were notified via email. Ex. 2 at 27 (citing Ex. 35 at 61:14–22). These pharmacy managers and supervisors would then review the flagged order to determine whether it was suspicious: during this review, they used relevant information, including the pharmacy's dispensing history, monthly trend reports, and manual inventory adjustment reports. Ex. 2 at 27 (citing Ex. 35 at 61:23–63:4, 64:6–65:12).

Similarly, PIMS 2.0 and E-Supply Link automatically emailed pharmacy supervisors for the ordering store, notifying them of any flagged order items. Supervisors were tasked with reviewing the store's orders and determining whether they were suspicious. *See* Ex. 34 at 138:6–23; Ex. 35 at 62:24–63:16; Ex. 33 at 318:23–321:9; Ex. 16 at 74:11–21; Ex. 2 at 29, 33; Ex. 10 ¶ 12; Ex. 33 at Ex. 28 (PDF pages 12–16) (June 2018 email discussing and attaching "CS Threshold Training for Pharmacy Supervisors").[12] If a Supervisor identified a flagged item as suspicious, the Supervisor was required to notify his or her pharmacy operations manager and Chris Hewell, Publix's Procurement Director. Ex. 10 ¶ 13; Ex. 45 at 140741. As part of this process, pharmacy supervisors could receive requests to increase thresholds from the stores they oversaw, and pharmacy supervisors were required to ensure any requested increase was legitimate and that the pharmacy had no suspicious activity. Ex. 34 at 292:1–5.

Publix ensured pharmacy supervisors had a wealth of information they could consider when applying their professional judgment to the review of flagged orders: For example, they could review prescription activity tracked in Publix's pharmacy dispensing software, manual inventory and adjustment reports, and monthly "CII Pull Reports" summarizing the store's dispensing data for various Schedule II drugs. Ex. 2 at 29; Ex. 34 at 292:12–18; Ex. 35 at 64:6–

[12] It is therefore false to assert, as Cobb County does, that "prior to 2019 …. there was no one evaluating whether or not the [flagged] order was indeed suspicious." Br. 13.

65:12; Ex. 33 at 115:22–116:24, 320:1–321:9; Ex. 16 at 87:4–89:9; Ex. 12 at 83:11–87:19, 231:5–25. Using the CII Pull Reports, a pharmacy supervisor could compare the order and dispensing history for one pharmacy against other Publix pharmacies. Ex. 2 at 41; Ex. 33 at 114:3–116:24; Ex. 45 at 140742. In addition, supervisors relied on their personal knowledge of the stores they oversaw (and the relevant communities), which gave them an understanding of that pharmacy's business prior to receiving a threshold increase request. Ex. 34 at 294:18–24; Ex. 16 at 75:8–16.

Publix continued to task pharmacy supervisors with reviewing flagged orders until 2018, when it centralized the review of flagged orders and tasked that review to Diversion Analysts, a new position created as part of the overall centralization of the pharmacy compliance department. Ex. 34 at 138:6–23, 150:3–6; Ex. 30 at 65:13–18. And like the pharmacy supervisors, these analysts review orders to determine whether the pharmacy was filling illegitimate prescriptions and whether products were being diverted. Ex. 34 at 161:17–21.

3. Centralized controlled substance ordering system (CSOS) order review

Publix also implemented centralized CSOS Administrators to sign all CII Orders, and tasked them with reviewing all CII orders for reasonableness prior to signing. Ex. 10 ¶ 17; Ex. 45 at 140743. When CII orders were placed significantly above a store's prior usage levels, the CSOS administrator consulted internal data (*e.g.*, dispensing history, current inventory, and prescription hard copies) to determine if the quantity ordered was too high. Ex. 10 ¶ 17; Ex. 45 at 140743.

4. Additional anti-diversion processes

Publix further identified and prevented suspicious orders by distributing and reviewing CII pull reports monthly, making historic dispensing data available to pharmacists and supervisors to consult when dispensing, hiring educated and trained pharmacists, providing ongoing training to pharmacists under the supervision of pharmacy managers and supervisors, and engaging in other compliance reviews. *See* Ex. 2 at 29, 31, 37; Ex. 5 at 21-22, 38–39; Ex. 22.

III. Opioid Data Show Publix's Controls Against Diversion Are and Were Effective

Finally, a jury could easily find, based on the small number of opioids Publix distributed to its own stores, and that it dispensed within Cobb County, that the data demonstrate that Publix's controls against diversion are and were effective. DEA has consistently maintained that it cannot tell registrants *how* to design a SOM system because DEA's ultimate goal is to prevent diversion by detecting and avoiding "outliers" and "anomalies." *See, e.g.*, Ex. 44 at 96:16–97:1, 214:12–215:7; Ex. 9 at 84:9–86:4, 168:11–15. The data show Publix was *not* an outlier in Cobb County, collectively or on an individual store basis. Candice Rosevear, a data analytics and statistics expert, analyzed ARCOS and Publix dispensing data. That analysis, and the summary statistics she presents, demonstrate that, at a minimum, the data do not compel a jury to find that Publix had an ineffective system of controlling diversion during the period at issue (2006–2019). For example:

- For both dosage units and MME, the per-store average of opioids dispensed by Publix was consistently and significantly *lower* than the per-store average of all other retail pharmacies in Cobb County, in Georgia, and in the United States. *See* Ex. 3 at Ex. 3A (PDF page 107) and Ex. 3 at Exs. 4A and 4D (PDF pages 109, 112). The same is true for hydrocodone and oxycodone when measured individually. *See* Ex. 3 at Exs. 4B/4E and 4C/4F.
- Publix stores in Cobb County dispensed 98,199 opioid dosage units per year, on average. Lacey's Marietta Pharmacy (DEA NO. BM1893634), by far the largest single retail dispenser located in Cobb County (and not named as a defendant), dispensed 959,927 dosage units per year—nearly *ten times* the average per store of Publix. Ex. 3 at 28.
- Patients who filled opioid prescriptions at Publix typically filled drugs *other* than opioids (or benzodiazepines or muscle relaxers). Of those receiving opioid prescriptions, more than 90% *also* received a prescription for something other than one of those drugs. Ex. 3 at 35.

- Most patients who received opioids at Publix only ever received one opioid prescription. Only 9% of patients filling opioid scripts at Publix were dispensed six or more scripts of opioids over the 13-year time frame. Ex. 3 at 35.
- Only 2.7% of the total opiates dispensed at Publix's Cobb County stores were for 30mg of oxycodone, and another 2.8% were for 15mg oxycodone. Ex. 3 at Ex. 2B (PDF page 106). According to Mr. Rannazzisi, such drugs were the "gold standard for opioid use disorder people and also people who were illegally selling." Ex. 9 at 85:10–12.
- Publix pharmacies consistently dispensed lower-strength opioids on average compared to other pharmacies in Cobb County. Ex. 3 at 20, 26–28.
- From 2006 to 2019 Publix dispensed only 10% of the overall dosage units of opioids in Cobb County, and just 7.1% of the total MME. Ex. 3 at 21–22.
- Opioid prescriptions have consistently constituted a small portion of Publix's pharmacy business: From 2006 to 2019, more than 95% of prescriptions Publix filled in Cobb County were for *non-opioid* drugs. *See* Ex. 3 at 21; Ex. 3 at Exs 5.1 to 5.25 (store-by-store, and year-by-year, analysis showing percentage of opioids among total prescriptions dispensed).

Further, Mr. Rucker has opined that the data reveal that Publix's dispensing (and its corresponding self-distribution, as applicable) of opioids was "well below county, state and national averages" and that controlled substances constituted a "reasonable and unremarkable part of the overall dispensing at each of [Publix's] pharmacy locations in Cobb County." Ex. 2 at 20.

In sum, at all times, as both dispenser and distributor, Publix complied with its corporate duties under the CSA, the Georgia Controlled Substances Act, and all associated regulations.

Dated: August 9, 2024

Respectfully submitted,

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LOCAL RULE 7.1(f) CERTIFICATION

This brief, which has 40 pages, adheres to the limits for mass tort cases set forth in Local Rule 7.1(f).

Dated: August 9, 2024

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